



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

MU

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/769,695

01/30/2004

Shubh D. Sharma

70025-US04-129

8611

55506 7590 02/28/2007
PALATIN TECHNOLOGIES, INC.
4-C CEDAR BROOK DRIVE
CEDAR BROOK CORPORATE CENTER
CRANBURY, NJ 08512

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
----------------------------------------	-----------	---------------

3 MONTHS

02/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/769,695

Applicant(s)

SHARMA ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12-15,18-22,24-27 and 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 34-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-15,18-22,24-27 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-41 are pending.

Applicant's amendment filed December 12, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 10 and 22 have been amended, and claims 4, 11, 16, 17, 23, 28 and 29 have been cancelled. Claims 34-41 are non-elected inventions and withdrawn from consideration. Therefore, claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-33 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-33 under 35 U.S.C.112, first paragraph, scope of enablement, is withdrawn in view of applicants' amendment to the claims, applicant's cancellation of the claim, and applicant's response at page 10 in the amendment filed December 12, 2006.
3. The previous rejection of claims 1-9, 11 and 23 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment to the claims, applicant's cancellation of the claim, and applicant's response at page 10 in the amendment filed December 12, 2006.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

4. The previous rejection of claims 4, 11, 16, 17, 23, 18 and 29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-40 and 42-76 of co-pending Application No. 10/464,117, is withdrawn in view of applicant's cancellation of the claim in the amendment filed December 12, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1-3 and 5-9 are indefinite because of the use of the term “provided that any proline residue in the two residue positions immediately adjacent the amino-terminus side of C is substituted and any cysteine residue in R₁ is S-protected or substituted” or “provided that any cysteine residue in R₁ is S-protected or substituted”. The cited term renders the claim indefinite, it is not clear with what residue the cysteine residue in R₁ is substituted. Claim 1 recites the limitation "adjacent the amino-terminus side of C" in line 12. There is insufficient antecedent basis for this limitation in the claim, the claim recites “Z”. Claims 2-3 and 5-9 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
7. Claims 3, 13, 15, 25 and 27 are indefinite because of the use of the term “homolog”. The cited term renders the claim indefinite, it is not clear whether the homolog of L-cysteine or D-cysteine has SH group. It appears that the specification indicates the homolog of Cys is Gly, Ala or Ser or a Cys with S-protecting group (see paragraph bridging page 19 and 20). However, the homolog in claims 3, 15 and 27 requires SH group, and the homolog in claims 13 and 25 does not contain SH group.

Art Unit: 1656

8. Claims 14 and 26 are indefinite because of the use of the term "the proline residue is substituted with a homolog". The cited term renders the claim indefinite, it is not clear whether the homolog of proline has an NH group for metal chelation, e.g., hydroxyproline is a homolog of proline.

9. Claims 10, 12-15, 18-22, 24-27 and 30-33 are indefinite as to how the specific residues that binds to a target of interest in the primary sequence of parent polypeptide are determined. Claims 12-15, 18-22, 24-27 and 30-33 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate claims 10 and 22 have been amended to incorporate the limitations of claim 11 and 23 (page 10 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because although the claim recites the step of selecting the metallopeptides of the series exhibiting decreased binding to the target of interest, the claims do not indicate identification of the residues in the metallopeptides exhibiting decreased binding to the target of interest.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1656

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-21, 23, 24, 26-40, 42-56 and 58-76 of co-pending application No. 10/464,117 (based on the amended claims filed September 20, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-33 in the instant application disclose a method of determining the specific residues binding to a target of interest within a known parent polypeptide that binds to the target of interest, comprising the steps of: (a) providing a known parent polypeptide with primary structure consisting of n residues of 3-20; (b) constructing a first peptide of R_1 -Z- R_2 with R_1 , Z, R_2 each defined; (c) complexing the peptide of R_1 -Z- R_2 to a metal ion and forming R_1 -Z- R_2 metallopeptide; (d) screening R_1 -Z- R_2 metallopeptide for binding to the target of interest; (e) repeating steps (b) through (d), wherein the resulting R_1 -Z- R_2 metallopeptide differs in at least either R_1 or R_2 ; and (f) selecting the R_1 -Z- R_2 metallopeptide exhibiting decreased binding to the target of interest; or comprising the steps of making a series of peptides including the known primary sequences of the parent polypeptide of 3-20 residues and a single L- or D-3-mercapto amino acid residue inserted between the two positions (starting the second and third positions) or substituting at each residue (starting the third residue) of the primary sequence, complexing each peptide in the series with a metal ion, and determining the binding of each metallopeptide to the target of interest, and selecting the metalloptides exhibiting decreased binding to the target of interest. This is obvious variation in view of claims 1-3, 5-21, 23, 24, 26-40, 42-56 and 58-76 in

Art Unit: 1656

the co-pending application disclose a method of determining a secondary structure binding to a target of interest within a known parent polypeptide that binds to the target of interest, comprising the steps of: e.g., (a) providing a known parent polypeptide with primary structure consisting of n residues of 3-20; (b) constructing a first peptide of R_1 -C- R_2 with R_1 , C, R_2 each defined; (c) complexing the peptide of R_1 -C- R_2 to a metal ion and forming R_1 -C- R_2 metallopeptide; (d) screening R_1 -C- R_2 metallopeptide for binding to the target of interest; (e) repeating steps (b) through (d), wherein the resulting R_1 -C- R_2 metallopeptide differs in at least either R_1 or R_2 ; and (f) selecting the R_1 -C- R_2 metallopeptide exhibiting binding to the target of interest. Since both groups of claims are directed to a method of determining the secondary structure of the residues binding to a target of interest within a known parent polypeptide, thus, claims 1-3, 5-10, 12-15, 18-22, 24-27 and 30-33 in present application and claims 1-3, 5-21, 23, 24, 26-40, 42-56 and 58-76 in the co-pending application are obvious variations of a method of determining a secondary structure binding to a target of interest within a known parent polypeptide that binds to the target of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate if this case is otherwise in condition for allowance the rejection will be withdrawn provided that co-pending application No. 10/464,117 is not prior thereto allowed, and that Applicant reserves the right to raise defenses or objections to the rejection in the co-pending application (page 11 of the response).

Art Unit: 1656

Applicants' response has been considered, however, the arguments are not persuasive.

Since the instant application has a filing date of 1/30/04, while co-pending application 10/464,117 has an earlier filing date, and the claims of instant applications are not allowable, the rejection is maintained.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

February 23, 2007